

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) March 21, 2018
)

Sherr-Una Booker, an individual,)
)
Plaintiff,)
) CV-16-00474-PHX-DGC
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
)
Defendants.)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 5 A.M. SESSION

(Pages 900 - 950)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

For the Plaintiff:

Lopez McHugh
By: **RAMON ROSSI LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

Watkins Lourie Roll & Chance, PC
By: **ROBIN P. LOURIE**, ESQ.
Tower Place 200
3348 Peachtree Rd. NE
Atlanta, GA 30326

Faraci Lange, LLP
By: **HADLEY L. MATARAZZO**, ESQ.
28 E. Main St., Ste. 1100
Rochester, NY 14614

Babbitt & Johnson, PA
By: **JOSEPH R. JOHNSON**, ESQ.
1641 Worthington Rd., Ste. 100
W. Palm Beach, FL 33409

For Defendants:

Nelson Mullins Riley & Scarborough
By: **RICHARD B. NORTH, JR.**, ESQ.
By: **ELIZABETH C. HELM**, ESQ.
By: **BRANDEE J. KOWALZYK**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Snell & Wilmer
By: **JAMES R. CONDO**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

I N D E X

EXAMINATIONWITNESSPAGE

Video Testimony of Dr. D'Ayala	924
Video Testimony of Dr. Patel	926
Video Testimony of Dr. Kang	926
Video Testimony of Dr. Harvey	928
MICHAEL RANDALL	
Direct Examination By Mr. Lopez	929

EXHIBITS

<u>NUMBER</u>	<u>DESCRIPTION</u>	<u>PAGE</u>
2368	Medical Record: Radiology Consult Report 07/23/2014 (Kang's report re IR procedure)	926
2349	Medical Record: X-ray chest Gwinnett Medical 07/03/2014-report	926
1811	Patel Deposition, 03/22/2017, Exhibit A5 - Hospital chart, part of chart dealing with procedure by Kang	926
2355	Medical Record: Medical Records Gwinnett Medical -informed consent for IVC filter removal 07/23/2014	926

(Index of Exhibits Continued)

EXHIBITS

<u>NUMBER</u>	<u>DESCRIPTION</u>	<u>PAGE</u>
1806	Patel Deposition, 03/22/2017, Exhibit A13 - Office notes, Dr. Harvey re pleural effusion and pus in the jugular site 08/14/2014	926
1807	Patel Deposition, 03/22/2017, Exhibit A14 - Office notes, visit for chest pain 02/23/2015	926
2350	Medical Record: Medical Records Gwinnett Medical 07/03/2014-Consultation Notes of Kang	927
2361	Medical Record: Medical Records Gwinnett Medical-Op Note of Dr. Harvey open heart surgery 07/28/2014	928
2364	Medical Record: Medical Records Gwinnett Medical- Pathology Report - 07/29/2014	928
1332	Harvey Deposition, 06/20/2017, Exhibit 13 - Medical Record, Radiology report Gwinnett 07/24/2014-CT	928
1222	Ganser Deposition, 10/11/2016 - Exhibit 534 - PowerPoint Presentation for a meeting to analyze EVEREST and MAUDE data and provide justifications for proposed changes to G2 filter	941

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Thank you. Please be seated.

All right. Plaintiff's counsel, you wanted to raise the FDA warning letter issue.

MS. REED ZAIC: Yes, Your Honor. In the Court's order with regard to defendants' motion in limine to exclude the FDA warning letter of 2015, the Court's ruling excluded the letter with the potential exception of topics 3, 7, and 8.

We have met and conferred. I met and conferred with counsel for Bard. We've not been able to reach an agreement.

First issue I wanted to address is just some confusion with my reading of the Court's order.

On page 7 it states that the warning letter did not concern the G2 line of filters. However, the warning letter in section 3 mentions the G2 line of filters six or seven times. So with that regard, the warning letter did deal with the exact filter Ms. Booker received.

The last part of the Court's sentence says that the letter was issued long after Ms. Booker received her G2 filters. However, when I went back and pulled these complaint files dealing with these G2 filters, they were reports to Bard after Ms. Booker received her filter, yet it was still

08:32:00 1 retrospective. The complaints went back to 2010, of the ones
2 in the report. The further investigation, they reviewed
3 further complaints going back.

4 However, these complaints of G2 filter failures are
08:32:14 5 almost exactly the scenario of what Ms. Booker experienced in
6 that section or topic 3, paragraph C, deals with failed
7 attempts for removal and the lack of followup on subsequent
8 surgeries.

9 Also, during this time period of the complaints that
08:32:30 10 are pointed out in the warning letter, Ms. Booker still had
11 the filter in her. There's been testimony thus far in the
12 case about the lack of monitoring followup.

13 THE COURT: Still had the filter in when?

14 MS. REED ZAIC: Ms. Booker had her filter implanted
08:32:48 15 in 2007. The complaints that are in the warning letter are
16 after, but she still had it implanted in 2014.

17 THE COURT: Are you talking about the complaints
18 referred to in paragraph 3B?

19 MS. REED ZAIC: And 3C, Your Honor.

08:32:59 20 THE COURT: Okay. I obviously couldn't tell from
21 just the numbers what complaints they are. You're saying some
22 of those are G2 complaints?

23 MS. REED ZAIC: Yeah. So in paragraph B it's
24 embedded in there and it's a little hard to read and mixed in
08:33:10 25 with other filters, but in paragraph 3B they do -- the first

08:33:12 1 complaint is a G2 filter.

2 THE COURT: Yeah, I've got four -- I've got four G2s
3 highlighted in paragraph 3B.

4 MS. REED ZAIC: Correct. And in 3C, the complaints
08:33:21 5 are -- I've been able to identify the very first one by
6 looking at the complaint file. That is a G2.

7 This paragraph is a report of ten failures from the
8 same -- reported by the same provider. I was not able to
9 determine, because Bard's records don't reflect the followup
08:33:38 10 that reached a conclusion of which filters these were, but
11 it's the same provider reported at the exact same time and the
12 first one is verified as a G2. With that distinction, I have
13 to admit I cannot verify nine of the ten -- or, I'm sorry,
14 everything except the first one, which I did find was the G2.
08:33:56 15 But it is the same provider.

16 THE COURT: And that is 507112?

17 MS. REED ZAIC: Yes, sir. Yes, Your Honor.

18 I actually have a copy of the complaint if the Court
19 would look at it, if you would like to, but I did pull it and
08:34:09 20 find it.

21 So that was the first topic. I have a couple other
22 issues if we're going to take it topic by topic.

23 THE COURT: Well, let me give you a reaction on that
24 and let you respond.

08:34:19 25 When I looked at paragraph 3 back when the order was

08:34:21 1 entered, this is a letter that was written in 2015. At the
2 beginning of the second sentence in paragraph 3 it says, "Your
3 current procedures governing complaint investigations do not
4 ensure adequate evaluation."

08:34:40 5 So it looked to me as though it was talking about
6 whatever procedures were in place in 2015. And so it looked
7 to me like the criticism the FDA was giving Bard was the
8 complaint procedures you have in place today don't ensure
9 adequate evaluation.

08:34:58 10 The reason I said in the order it didn't concern the
11 G2 was there was nothing in the letter saying there's a
12 problem with the G2 or you haven't submitted enough
13 information on the G2.

08:35:17 14 Clearly 3B mentions four G2 filter complaints. But
15 it looked like to me when I read it as though it was talking
16 about 2015 procedures. But I'm interested in your thoughts on
17 that.

08:35:30 18 MS. REED ZAIC: So their SOPs for following up on
19 complaints are current. I would imagine, although I can't
20 say, the FDA was looking at the current one, but this is a
21 retrospective analysis and these complaints, although they had
22 one SOP in place in 2015 that maybe the FDA evaluated, these
23 complaints go back to implants as far back as 2010. And they
24 have a continuing duty to warn.

08:35:50 25 So although this warning letter didn't come out until

08:35:53 1 2015, and maybe they were looking at what they had in place
2 currently, these reports are relevant and the FDA pointing out
3 that they didn't do the appropriate followup and mismanaged
4 and didn't do root cause analysis, this goes back to
08:36:07 5 complaints that are the same filter and in section 3C deal
6 with the same injury that Ms. Booker experienced.

7 THE COURT: So let me ask you another question, if I
8 can. The earliest G2 complaint mentioned in paragraph 3B
9 appears to me, at least assuming numbers track
08:36:27 10 chronologically, would be complaint 443237, which is in the
11 second line of page 5. That's the lowest numbered complaint I
12 can see for a G2. Do you know when that complaint was
13 received by Bard?

14 MS. REED ZAIC: On march 19, 2013. There was no
08:36:48 15 record I could find within that complaint file that they were
16 able to collect an implantation date, so I don't know when
17 that was implanted with the G2 filter. It could have been as
18 early as 2005.

19 THE COURT: Did you say a moment ago that the
08:37:01 20 earliest complaints referred to in paragraph 3 are 2010?

21 MS. REED ZAIC: The implant dates were 2010. In
22 paragraph 3B, complaint number 446809, I show an implant date
23 I collected from the complaint file of April 2nd, 2010. That
24 was a G2X filter. Same delivery mode as Ms. Booker received.

08:37:27 25 THE COURT: When was the complaint received?

08:37:28 1 MS. REED ZAIC: Awareness date was March -- excuse
2 me. April of 2013. According to the records.

3 THE COURT: Okay. So here's the question I guess I
4 have for you: As I understand the letter in light of the
08:37:46 5 additional information you provided, we have the FDA in 2015
6 telling Bard that its current procedures for following up on
7 complaints are inadequate and the earliest complaint its
8 dealing with is a 2013 complaint of the G2, as far as we know.
9 Explain to me your view of why inadequate handling of
08:38:15 10 complaints in 2013 through 2015 are relevant to Ms. Booker's
11 case.

12 MS. REED ZAIC: Because she still had her filter
13 implanted in her. The FDA is going back and seeing a problem
14 that retrospectively has been going on for quite some time
08:38:31 15 during the period that the plaintiff had the filter implanted
16 in her.

17 We've had testimony about their lack of warning to
18 doctors to continue to monitor. The FDA is going in and
19 finding a problem with the way that they're collecting their
08:38:43 20 complaints and our witnesses are being cross-examined on rates
21 and numbers, and only a certain amount of numbers that have
22 been reported at a certain time I think becomes relevant.
23 They're not collecting the appropriate information and an
24 agency has to come in and tell them retrospectively that
08:39:01 25 they've been doing it going back several years.

08:39:04 1 I would also add, Your Honor, that with regard to --
2 I also believe this is relevant to punitive damages. A lack
3 of compliance with the federal regulation is relevant to a
4 punitive damages claim and it's probative whether Bard acted
08:39:17 5 with conscious indifference to the dangers posed by the
6 device. There's specifically a regulation pointed out in
7 topic 3 that they're clearly in violation of.

8 THE COURT: Where are you looking at in topic 3? Are
9 you talking about before paragraph A?

08:39:38 10 MS. REED ZAIC: Yes, the opening paragraph that
11 addresses paragraphs A, B, C. It says failure to establish
12 and maintain procedures for receiving, reviewing, and
13 evaluating complaints as required by 21 CFR 820.198(a).

14 THE COURT: So let me make sure I understand your
08:39:56 15 argument.

16 It seems to me you are making two points. Maybe
17 more. But one is you would want to argue to the jury that
18 while Ms. Booker still had her filter before it was removed in
19 2014, Bard was receiving complaints about the G2 and was not
08:40:17 20 handling them properly, as was indicated in 2015 when the FDA
21 told them that, which is evidence that during the time the
22 filter was in Ms. Booker Bard was not adequately tracking and
23 dealing with the problems of the G2.

24 The second argument, I think, is that this section 3
08:40:41 25 shows that Bard was not complying with regulations governing

08:40:47 1 complaint-handling procedures, which bears on the punitive
2 damages question.

3 MS. REED ZAIC: Yes, Your Honor. And the first point
4 with regard to that aspect of failing to warn, Mr. North was
08:40:57 5 saying yesterday, cross-examining witnesses, nothing was
6 preventing doctors from removing these devices while they were
7 in violation of these regulations, which the agency didn't
8 discover until 2015.

9 THE COURT: Okay. Were there other points you wanted
08:41:11 10 to make on the letter?

11 MS. REED ZAIC: Well, there are two other paragraphs.
12 They're not as robust as what we're pointing out here. The
13 paragraph number 7 is with regard to -- pardon me; the
14 government says a lot. Paragraph 7 is a similar argument.
08:41:35 15 They're in violation of medical device reporting standards,
16 specifically U.S.C. 352 section T, as in tango, 2.

17 This is specific to the Denali filter. I wanted to
18 bring it to Your Honor's attention in that our expert
19 yesterday was cross-examined on the fact that he still uses
08:41:57 20 Bard products, and it was the Denali filter.

21 And then, quickly, paragraph 8 deals with failure to
22 obtain information, again in violation of regulations, on
23 simple things such as age, time of the event, date of birth.
24 So it sort of wraps back into paragraph 3 as this is a
08:42:16 25 continuing problem.

08:42:18 1 THE COURT: When I read paragraph 8, it appeared to
2 me what they were saying is you submitted MBRs -- MDRs, you
3 just didn't include all of the relevant information, such as
4 age of the patient; is that right?

08:42:35 5 MS. REED ZAIC: Yes, Your Honor, but I think it
6 indicates they're not collecting it. They're not acting in a
7 manner to be able to vigilantly collect this information,
8 which is part of the problem in paragraph 3.

9 THE COURT: And tell me what you think you should be
08:42:48 10 allowed to do with this warning letter.

11 MS. REED ZAIC: If it comes up with regard to our
12 failure to warn argument, like I said, this dovetails back
13 into paragraph 3 in that this is a continuing process.

14 If they're going to continue to cross-examine our
08:43:02 15 witnesses about still using Bard products and Denali in this
16 day and age, even after 2015, as of 2015 they were still in
17 violation of doing the appropriate post-marketing surveillance
18 and collection methods.

19 THE COURT: And would you be seeking to put this
08:43:16 20 letter in evidence? Is that what you're proposing?

21 MS. REED ZAIC: Yes, Your Honor.

22 THE COURT: Or at least the portions that are
23 relevant.

24 MS. REED ZAIC: Yes, Your Honor. When appropriate.

08:43:24 25 THE COURT: Okay. All right. Thank you.

08:43:28 1 MR. NORTH: Thank you, Your Honor. I'd like to start
2 off by addressing the timing issue the Court raised. This is
3 criticisms of the current practices. I think that is very
4 important because this is not the first and only FDA
08:43:40 5 inspection Bard has had, and if this Pandora's box regarding
6 this letter comes out or is opened, what is going to happen is
7 we're going to be presenting a lot of evidence of many
8 inspections that have occurred in the past involving Bard's
9 complaint procedures where the FDA found no problems, no
08:44:00 10 citations, no warning letters.

11 This is, in fact, focused on the current practice,
12 practices, at the time of these inspections, long after the
13 implant in this case.

14 Now, it is difficult to treat these alleged
08:44:15 15 violations with a broad brush, I believe, because all of them
16 are very specific with very specific issues surrounding them.
17 And I believe when you look at the specific issues on each of
18 these citations or points raised by the FDA, it becomes clear
19 that they're not relevant in the least to Ms. Booker's design
08:44:36 20 or failure to warn claims.

21 Turning first to 3A, 3A has to do with inadequate
22 procedures, allegedly, about evaluating root cause of
23 complaints regarding component suppliers.

24 This is not -- the FDA doesn't say this specifically,
08:44:54 25 but this almost certainly has to do with Denali. Denali is

08:44:59 1 manufactured by parts brought on from component suppliers.

2 The G2 was manufactured from scratch in house. For the most
3 part.

4 So it appears that 3A has to do with the Denali and
08:45:15 5 not the G2.

6 Further, 3A does not involve any failure to report
7 incidents to the FDA. It merely talks about how the company's
8 investigating root cause regarding component suppliers. And,
9 again, we fail to see how that has to do with a design defect
08:45:35 10 claim or the warning claim with the G2.

11 In 8B, this involves eight complaints that were,
12 according to the FDA, mischaracterized as a malfunction when
13 they should have been a serious injury or death. And only one
14 involved a death. And if we have to get into this, the
08:45:55 15 evidence will show that in that complaint file it marked
16 "malfunction" in one portion of the complaint file and "death"
17 in another portion. It was a clerical error.

18 But importantly, all eight complaints referenced in
19 3B were, in fact, reported to the FDA and were in the MAUDE
08:46:16 20 database. The only question was, with those, how Bard had
21 characterized it on the complaint file.

22 Again, this is in the 2013-onward time period, far
23 beyond the implant in this case.

24 8C all involved unsuccessful retrieval procedures.

08:46:40 25 All came from a single doctor. All involved attempted

08:46:43 1 percutaneous removals. And all involved no patient injury
2 when the investigation was complete.

3 If you look at all of the follow-up materials Bard
4 produced, none of these involve a patient injury. All of
08:46:59 5 these are six to eight years after the implant here. And it's
6 difficult to see how this has any relevance to the warning
7 claim or the design defect claim.

8 As Ms. Zaic just mentioned with topic number 7 in the
9 FDA warning letter, that has to do with the Denali filter.

08:47:24 10 The four complaints referenced there all had to do with
11 deployment issues where there were difficulty in deploying the
12 filter and there were no patient injuries in any of those.

13 And then when you turn to 8, as the court just
14 mentioned, those were all complaints that were reported to the
08:47:43 15 FDA, and the FDA's criticism was that they lack sufficient
16 information concerning the age or date of birth and similar
17 type attributes of the patient involved.

18 None of these issues raised by the FDA have to do
19 with whether the Bard filter was defective when it was
08:48:04 20 designed and whether Bard failed to warn.

21 Also, Your Honor, I don't think it's appropriate to
22 try to justify this on the basis it supports some punitive
23 damage claim.

24 Punitive damages are supposed to be based, and I
08:48:20 25 think this is a constitutional principle represented by the

08:48:23 1 Supreme Court, on conduct related to the injury to the
2 particular plaintiff. That's the conduct of Bard regarding
3 the design and warning to Ms. Booker. With regard to
4 Ms. Booker.

08:48:39 5 What the FDA may have said or done regarding
6 complaint procedures in 2015 is simply not relevant to the
7 conduct that allegedly injured her.

8 If we were arguing that our compliance with the FDA
9 regulations in 2015 with regard to Denali was somehow
08:49:03 10 probative as to our defense of punitive damages, maybe they
11 would have an argument there. But when we're going to present
12 our compliance defense, it is based upon our conduct up until
13 what happened with Ms. Booker. And the fact that -- and
14 regarding the G2 filter and not whether complaint file issues
08:49:25 15 existed in 2015.

16 Lastly, Your Honor, I think the most important point
17 here is regardless of the criticisms of the FDA, Bard's
18 internal data, Bard's trending of complaints, and the
19 testimony is unequivocal and uncontradicted on this point,
08:49:46 20 Bard's trending always included every single complaint
21 mentioned by the FDA, every single type of complaint mentioned
22 by the FDA. Bard trends on complaints, whether it's
23 ultimately reported to the FDA or not reported to the FDA;
24 whether there's a serious injury or not a serious injury;
08:50:05 25 whether it's characterized as a malfunction, a death, a

08:50:10 1 serious injury. However characterized, Bard's trending
2 includes the entire universe of complaints here.

3 We believe this is -- therefore, all of these issues
4 are irrelevant under 402.

08:50:28 5 And even if there was some minimal probative value,
6 this is a highly inflammatory issue and I think that it would
7 warrant exclusion under Rule 403.

8 If it would help the Court, we would be happy to
9 file, like, a two-page brief in the next 24 hours detailing
08:50:47 10 the minutia I just tried to summarize about each of these
11 categories as far as what they deal with. But otherwise,
12 that's our argument.

13 THE COURT: All right.

14 MS. REED ZAIC: Your Honor, I agree with Mr. North
08:50:59 15 that what happened to Ms. Booker up until -- what happened up
16 until the time Ms. Booker had her injury and her surgery is
17 relevant, and that includes complaints that are mentioned in
18 the FDA warning letter.

19 And I want to point out that in reviewing the FDA
08:51:15 20 warning letter, these are inspections. As far as we know,
21 these are random selections of complaints. These aren't they
22 walked in and reviewed every single complaint or got into
23 their TrackWise database and looked through. These are random
24 selections. There was then a retrospective review going back
08:51:32 25 and there were over 200 mischaracterizations between

08:51:35 1 malfunction and serious injuries.

2 Defendants go back and forth whether MAUDE is
3 relevant, not relevant. There's cross-examination and there's
4 direct examination with physicians with regard to MAUDE and if
08:51:49 5 something is in MAUDE as a malfunction and not a serious
6 injury, that is certainly relevant, and the fact an agency had
7 to point it out is highly probative of that matter.

8 More specifically in this case, Bard is trying to
9 shift the blame to the nonparty physicians. At the same time
08:52:06 10 they're saying there's no reason why these doctors couldn't
11 take these out. Meanwhile, they weren't collecting the
12 complaint information that defendants are saying they were
13 tracking and trending. They were not sharing their tracking
14 and trending with physicians. The MAUDE database is public
08:52:20 15 and it was not -- and their complaint handling system was not
16 making it an accurate representation of what was going on
17 inside the company. They weren't sharing their tracking and
18 trending. MAUDE would have been appropriate. The FDA found
19 it.

08:52:34 20 Also, I believe the defendants have opened the door
21 on this issue when they're cross-examining expert witnesses
22 with regard to their credibility and the current devices that
23 they use, presumably to make the argument that if they're
24 still using Bard devices then everything should be okay, then
08:52:50 25 these sections about Denali become more relevant because of

08:52:53 1 there were issues with the way they were tracking and trending
2 and dealing with their Denali safety profile.

3 I believe that's it.

4 THE COURT: Okay. I want to think about this issue.

08:53:06 5 Yes, Mr. North.

6 MR. NORTH: Can I make two very quick points, Your
7 Honor?

8 THE COURT: Yes.

9 MR. NORTH: The first is that, contrary to what
08:53:13 10 Ms. Zaic said, these inspectors downloaded the entire
11 complaint database and took it with them and reviewed -- they
12 had access to everything.

13 The second point is I'm concerned about what allowing
14 the warning letter in -- the predicament it puts us in, into
08:53:31 15 potentially what is, frankly, an unsavory topic, but there is
16 clear evidence in the FDA documents we have received that this
17 inspection occurred after calls from various plaintiffs'
18 attorneys to the FDA saying that we weren't reporting
19 thousands of complaints. And there is evidence of a clear
08:53:54 20 cause and effect there. We don't really want to get into
21 that. I don't think it's helpful to the trial. But it's
22 going to be a difficult predicament for us to consider if
23 evidence of this warning letter comes in since we have such
24 clear evidence from the FDA that not long beforehand they were
08:54:12 25 approached by Mr. Dalimonte and other plaintiffs' lawyers with

08:54:17 1 complaints about our trending and tracking.

2 THE COURT: All right. Let me think about this.

3 MS. REED ZAIC: Your Honor --

4 THE COURT: I probably will come back with additional
08:54:25 5 questions.

6 Did you want to say one final thing?

7 MS. REED ZAIC: Yes, Your Honor. I cannot
8 cross-examine the FDA on what they did and didn't do and what
9 happened inside Bard when they showed up for an inspection.

08:54:36 10 With regard to the unsavory nature, I believe, time
11 permitting, Ms. Booker's going to take the stand today and
12 we'll talk about a lot of unsavory things that happened to her
13 because of this filter and the issues that are pointed out in
14 the FDA letter.

08:54:48 15 Also, with regard to attorney involvement in this, I
16 believe discovery was served and answered and whether that --
17 the people sitting here at counsel table responded to
18 discovery. That shouldn't even be an issue. This letter was
19 issued. It is relevant. If you'd like a two page, Your
08:55:07 20 Honor, that's fine as well.

21 Thank you, Your Honor.

22 THE COURT: Okay. I'm going to take this under
23 advisement.

24 Are there any other matters we need to address before
08:55:16 25 we get the jury?

08:55:17 1 MR. LOPEZ: There are, Your Honor. I don't want
2 delay the jury, but I just want give the Court a heads up.

3 You'll recall that we had a conversation before the
4 trial started and I was -- we were very concerned on the
08:55:29 5 plaintiff side about the time available to us and I asked for
6 extra time, I asked for another day, asked for several more
7 hours. We've got a problem with time. I know we can't talk
8 about it now, but I'd like to talk about it at the noon hour.

9 We've already taken down three experts in this case
08:55:45 10 that we wanted to call because we're trying to squeeze this
11 case into a very tight window.

12 We can finish our case probably by tomorrow, but it's
13 going to leave us about four hours for the defense case and to
14 final argue and do the punitive damage phase.

08:56:02 15 We need, at a minimum, another three hours for us to
16 be able to squeeze what we think is the most important
17 evidence in this case. Otherwise we're not going to be able
18 to put on a complete case nor be able to cross-examine
19 appropriately in the defense part of the case.

08:56:18 20 I know it's not something we can talk about now, Your
21 Honor, but if we can talk about it after today, at the end of
22 the day or during the noon hour or maybe break a little early.
23 I can tell you -- I mean, I'll start with the fact we took
24 down three experts, including our FDA expert, to try to fit
08:56:34 25 this case into a very, very tight window.

08:56:36 1 And I know we got that extra day back on Monday. I
2 know the purpose for which you did that. And we're trying.
3 But it's not going to happen. I mean, we've cut our
4 depositions four, five times. We've taken out probably eight
08:56:50 5 or nine that we intended to play. And we can't do it. I
6 mean, I've got to cross-examine two really important witnesses
7 today and I don't want to worry about whether or not I can
8 have a full cross-examination of them. I'm worried about
9 that. Because if I do that then it's going to sacrifice what
08:57:05 10 we want to do in the last two or three hours of our trials.

11 THE COURT: Well, I understand what you've said. You
12 know the constraints we're up against in terms of being locked
13 into these days.

14 MR. LOPEZ: I do.

08:57:16 15 THE COURT: I do want to have time for the jury to
16 deliberate.

17 I will say there's been some repetition in your case.
18 I think for the most part it's been efficient, but there's
19 been many repetitive questions and some cumulative evidence.
08:57:28 20 I think you could have saved some time. But that's easy for
21 me to say; I'm not in your chair.

22 We are gaining about 15 or 20 minutes a day, so we'll
23 have a few extra hours by the time we get to next week. But
24 we do have the constraints we're up against.

08:57:48 25 MR. LOPEZ: I understand.

08:57:49 1 THE COURT: I can't hold court on Saturday.

2 MR. LOPEZ: I can reassure you one thing. The issues
3 you just mentioned about us being repetitive and going over
4 our time, we're paying the price for that. We're cutting out
08:57:59 5 things because -- and it is true, when you get up and start
6 cross-examining someone, the last thing you think about is the
7 clock.

8 We recognize that because of some of that we probably
9 could have saved several minutes there, but certainly not
08:58:15 10 enough to warrant us being able to put on a full case.

11 Like I said, we've already taken down three experts.
12 We've sent two of them home this week.

13 THE COURT: Okay.

14 MR. LOPEZ: Thank you, Your Honor.

08:58:27 15 MR. NORTH: Your Honor, I understand what Mr. Lopez
16 is saying, I just want to make a couple comments.

17 They've made strategic choices as to what they put on
18 along the way. Some of them -- they have their strategy, it's
19 not mine to question them. They spent two hours
08:58:42 20 cross-examining an engineer whose involvement was only with
21 two tests regarding the Recovery filter. That was their
22 choice.

23 The problem I have is any change in the time
24 allocations of any significance now unduly prejudices the
08:58:56 25 defendant, in my view, because we have made strategic choices

08:59:00 1 all along as to how long we would cross-examine witnesses, how
2 long we would spend doing certain deposition designations with
3 these time constraints in mind.

4 THE COURT: Okay. I understand what you both have
08:59:12 5 said.

6 We're going to bring the jury in at this time.

7 Go ahead, Traci.

8 Are we going to start with the same deposition being
9 played?

08:59:20 10 MR. LOPEZ: Yes, Your Honor.

11 (The jury entered the courtroom.)

12 THE COURT: Morning, ladies and gentlemen.

13 JURORS: Morning.

14 THE COURT: Thank you for being here. Go ahead and
09:00:32 15 have a seat.

16 We're going to pick up this morning where we left off
17 last evening, which is with the deposition of Dr. D'Ayala
18 being played.

19 So plaintiff's counsel, you may proceed.

09:00:42 20 (Video testimony played.)

21 MR. LOPEZ: That concludes that video.

22 THE COURT: All right. Your next witness.

23 MS. REED ZAIC: Yes. It is Dr. Patel, by video. I'm
24 going to do an intro as soon as I find it. I apologize.

09:31:35 25 Your Honor, again, this is our agreed upon

09:31:38 1 introduction, to save time on the tape.

2 Dr. Salil Patel is board certified in internal
3 medicine, cardiovascular diseases, nuclear cardiology, and
4 cardiovascular CT, and is employed at Gwinnett Cardiology
09:31:53 5 Services in Lawrenceville, Georgia, since 2016.

6 He's served as chief of the Department of Medicine at
7 Gwinnett Medical Center.

8 Dr. Patel graduated from Ohio State University
9 College of Medicine in 1996 and completed fellowships in
09:32:07 10 cardiovascular diseases and cardiac MRI in 2002.

11 Dr. Patel is Sheri Booker's cardiologist.

12 At this time, Your Honor, I'd like to list the
13 exhibits that will be displayed in the video and move them
14 into evidence.

09:32:23 15 Trial Exhibit 2368, Deposition Exhibit A, as in
16 alpha, 2.

17 Trial Exhibit 2349, Deposition Exhibit A3.

18 Trial Exhibit 1811, Deposition Exhibit A5.

19 Trial Exhibit 2355, Deposition Exhibit A7.

09:32:48 20 Trial Exhibit 2368, which is Deposition Exhibit A10.

21 Trial Exhibit 1806, which is Deposition Exhibit A13.

22 And Trial Exhibit 1807, Exhibit A15.

23 Thank you.

24 THE COURT: And you're moving all of those into
09:33:10 25 evidence?

09:33:11 1 MS. REED ZAIC: Yes, Your Honor.

2 THE COURT: Is there any objection?

3 MS. HELM: No, Your Honor.

4 THE COURT: All right, those exhibits are admitted.

09:33:20 5 (Exhibits 2368, 2349, 1811, 2355, 1806, 1807 admitted.)

6 (Video testimony played.)

7 MS. REED ZAIC: Apologize, Your Honor. I believe my

8 co-counsel took the summary out the door.

9 THE COURT: Ladies and gentlemen, if you want to

10:13:45 10 stand up for a minute, feel free, while we're finding the

11 documents.

12 MS. REED ZAIC: The next --

13 THE COURT: All right. Thanks.

14 MS. REED ZAIC: The next witness will be by video.

10:14:16 15 It is Dr. Brandon Kang. He's a board certified radiologist

16 and diagnostic radiologist. He is chief of radiology and

17 director of interventional radiology at North Metropolitan

18 Radiology Associates in Georgia.

19 Dr. Kang graduated from the University of Tennessee

10:14:32 20 Medical School in 1999 and completed a fellowship at Emory

21 University Hospital in 2005.

22 (Video testimony played.)

23 THE COURT: Counsel, let's stop the video, please.

24 We'll take our morning break, ladies and gentlemen,

10:30:04 25 and resume at 9:45.

10:30:07 1 (The jury exited the courtroom at 10:30.)
2 (Recess taken from 10:30 to 10:45. Proceedings resumed
3 with the jury present.
4 THE COURT: Thank you. Please be seated.
10:46:14 5 You may continue, Counsel.
6 (Video testimony resumed.)
7 MS. REED ZAIC: Your Honor, I'd like to move into
8 evidence three exhibits during the Kang deposition.
9 Trial Exhibit 2350, Deposition Exhibit 4.
11:05:37 10 Trial Exhibit 2368, Deposition Exhibit 7.
11 And trial Exhibit 2349, Deposition Exhibit 10.
12 THE COURTROOM DEPUTY: Two of those have been
13 previously admitted.
14 THE COURT: Apparently two of those have been
11:05:54 15 admitted.
16 Which of those?
17 THE COURTROOM DEPUTY: 2368 and 2349.
18 THE COURT: Any objection to 2350?
19 MS. HELM: No, Your Honor.
11:06:04 20 THE COURT: All right. That exhibit is admitted.
21 (Exhibit 2350 admitted.)
22 MS. REED ZAIC: Thank you, Your Honor.
23 The next witness by videotape will be Dr. Richard
24 Harvey. He's a specialist in cardiac, vascular, and thoracic
11:06:13 25 surgery at the cardiovascular and thoracic surgeons Gwinnet

11:06:17 1 Medical Group.

2 He went to medical school at University of
3 Mississippi School of Medicine and he completed his general
4 surgery training at Mercer University. He returned to the
11:06:27 5 University of Mississippi to complete his residency in
6 cardiothoracic surgery.

7 Dr. Harvey is a diplomat of the American Board of
8 Thoracic Surgery as well as a member of the American College
9 of Surgeons, Society of Thoracic Surgeons, and Alpha Omega
11:06:45 10 Alpha.

11 I'd like to move into evidence three exhibits
12 associated with his deposition.

13 Exhibit 2361, which is Deposition Exhibit 7.

14 2364, Deposition Exhibit 8.

11:07:05 15 And 1332, Deposition Exhibit 13.

16 THE COURT: Any objection?

17 MS. HELM: None, Your Honor.

18 THE COURT: Those exhibits are admitted.

19 (Exhibits 2361, 2364, and 1332 admitted.)

11:15:47 20 MS. REED ZAIC: Thank you.

21 (Video testimony played.)

22 MR. LOPEZ: Your Honor, at this time plaintiffs call
23 Mr. Michael Randall.

24 THE COURT: If you'd like to stand up, ladies and
11:37:55 25 gentlemen, while he's coming in, feel free.

DIRECT EXAMINATION - MICHAEL RANDALL

11:38:31 1 THE COURTROOM DEPUTY: If you'll stand right here and
2 raise your right hand, please.

3 MR. LOPEZ: May I proceed Your Honor? Thank you.

4 **MICHAEL RANDALL,**

11:38:46 5 called as a witness herein, after having been first duly sworn
6 or affirmed, was examined and testified as follows:

7 D I R E C T E X A M I N A T I O N

8 BY MR. LOPEZ:

9 Q Good morning.

11:39:04 10 A Good morning. How are you?

11 Q I think we may have met, but maybe not. You had your
12 deposition taken in this case?

13 A I had a deposition taken. I don't know if it was for this
14 case.

11:39:15 15 Q Have you had more than one deposition taken in a Bard IVC
16 filter case?

17 A Two.

18 Q I apologize. Could you introduce yourself to the jury and
19 tell them who you are, where you work.

11:39:36 20 A Sure.

21 Q And your position.

22 A I'm Michael Randall. I currently am the director of
23 research and development for Bard Peripheral Vascular. I
24 started with Bard back in 2006 and I worked on vena cava
11:39:53 25 filters. Came over as a senior engineer and progressed and

DIRECT EXAMINATION - MICHAEL RANDALL

11:39:57 1 now I'm a director.

2 Q And you're still employed there?

3 A Yes, I am.

4 Q And before today were you provided with some documents we
11:40:07 5 had given to counsel for Bard that were the type --

6 potentially the documents we would be using with you today?

7 A Yes.

8 Q And you've had a chance to look at those?

9 A Yes.

11:40:18 10 Q You've had a chance to prepare today for potentially
11 responding to some of those documents?

12 A Yes.

13 Q So the documents I'm going to show you, as long as they
14 were in the same material, they're not going to be a surprise
11:40:31 15 to you, today; right?

16 A They shouldn't.

17 Q You've had had an opportunity to read them from cover to
18 cover?

19 A It was a lot of information, so I tried to do my best to
11:40:41 20 get through it as fast as I could.

21 Q I promise we're not going to use nearly all of those.

22 MR. LOPEZ: Your Honor, this is his deposition.

23 BY MR. LOPEZ:

24 Q That's your February 2nd, 2007, deposition, and that's the
11:41:02 25 one that we'll probably be referring to today. And you have

DIRECT EXAMINATION - MICHAEL RANDALL

11:41:05 1 it available to you in the event you need to refer to it or I
2 need to remind you of something, okay?

3 A Okay.

4 Q So when you joined Bard in 2006, was there an immediate
11:41:20 5 issue or crisis with respect to one of its IVC filters they
6 assigned you to?

7 A No, there was no crisis when I joined Bard. When I came
8 over I worked in two franchises. I was doing PTA and because
9 I had experience in Nitinol, which is what the filters are
11:41:39 10 made of, I was able to work on the filter franchise.

11 Q And when did you actually start getting assignments or
12 given some responsibility to deal with the Bard IVC filters?

13 A I think it was 2007, 2008 when I started working on an
14 actual project. That was the G2 Express project.

11:42:05 15 Q And at the time there was already an IVC filter
16 manufactured by Bard and sold by Bard called the G2; correct?

17 A Correct.

18 Q So let's -- I want to make something -- you can make
19 something clear for us. Any retrievable device that Bard
11:42:22 20 sells is first and foremost a permanent device; right?

21 A Yes, I believe they all have permanent indication first.

22 Q And the most important thing about whether you call it a
23 permanent device or retrievable device, it's the strength and
24 stability and safety within a patient. True?

11:42:42 25 A I'm sorry, can you repeat that.

DIRECT EXAMINATION - MICHAEL RANDALL

11:42:44 1 Q Most important thing about these filters, whether they're
2 permanent or retrievable, once they get implanted they need to
3 stay where they're put and not break and not cause harm.

4 Agree with that?

11:42:56 5 A That's one of the things that is important for filters.

6 Q I asked you whether or not it was the most important
7 thing.

8 A I don't necessarily think it is the most important thing.
9 I think it's one of them.

11:43:09 10 Q Well, would you agree with me that it's important that
11 when you're trying to prevent a risk that you don't introduce
12 new risks into the patient? Maybe a risk that might be worse
13 than the risk you're trying to prevent?

14 A That's our goal is to really design something that's going
11:43:28 15 to be efficacious but then also safe. So we're striving for
16 that.

17 Q Now, you mentioned the G2X. The G2X is a G2 filter with a
18 hook on top?

19 A Yes, it is.

11:43:43 20 Q And in order for you to work on the G2X, wouldn't you have
21 had to have educated yourself on what was going on with the
22 G2?

23 A So my scope on the G2X project was essentially taking the
24 G2 filter, which had like a bullet tip on it, and instead of
11:44:01 25 having a bullet tip we had a tip that had a hook and to put

DIRECT EXAMINATION - MICHAEL RANDALL

11:44:06 1 that on the filter. So from an engineering perspective, I was
2 concerned with how to attach it and weld it.

3 Q Okay. I don't think you answered my question. Maybe it
4 was my fault.

11:44:16 5 A Sorry.

6 Q I asked you since you were going to be working on the G2X
7 project did you spend some time educating yourself on the
8 history and some of the details about the G2X itself -- I'm
9 sorry about the G2 device?

11:44:30 10 A No, not at that time.

11 Q And at some point in time did you?

12 A Yes, when it was the next filter platform that we were
13 going to start working on and improve.

14 Q When did you look at the platform of the G2 when you were
11:44:46 15 going to start working on the next generation beyond the G2X?

16 A That would be the project called Eclipse.

17 Q Okay. And were you in charge of that project?

18 A I was project leader at one point and so was -- and then
19 it went to someone else. So I didn't have sole responsibility
11:45:04 20 for it, but I was one -- I was the initial project leader.

21 Q When you were working -- prior to that time, and when you
22 first started at Bard, did you know that there was a clinical
23 trial going on for the retrievability of the G2?

24 A Yes, I knew there was a clinical trying going on.

11:45:26 25 Q Called EVEREST?

DIRECT EXAMINATION - MICHAEL RANDALL

11:45:27 1 A Yes.

2 Q Did you have any participation in that trial?

3 A No.

4 Q And then was Bard successful in getting clearance for the
11:45:39 5 G2X?

6 A Yes.

7 Q And you were involved in that; right?

8 A Yes.

9 Q And the G2X required a submission to the FDA under 510(k)
11:45:48 10 to get clearance for the G2X to become the new generation of
11 the G2; correct?

12 A It was a variation of the G2, yes.

13 Q So the G2's been on the market, what, since late 2005 and
14 the next time you go to the FDA with a change in the design of
11:46:14 15 the G2X is in 2008; is that right?

16 A That sounds right. I'm not sure exactly when we got
17 approval for it. During that time frame.

18 Q And so during that period of time between late 2005 and
19 2008 when you designed the G2 so you could put a hook at the
11:46:38 20 end of it, were there any other discussions going on at Bard
21 that maybe there ought to be some other design changes to
22 incorporate into the G2 since we're going to be submitting
23 something to the FDA in 2008 anyway?

24 A So I started at Bard in 2006, in April, so I don't know
11:46:56 25 from 2005 to April 2006. And I'm not sure what the

DIRECT EXAMINATION - MICHAEL RANDALL

11:47:02 1 discussions were at the time when I first started. I was a
2 senior engineer. I really didn't have a whole lot of
3 responsibility. I was an individual contributor.

4 Q But there was a point in time when you were looking at
11:47:14 5 redesigning the G2 and the G2X to make it the Eclipse that you
6 went back and you looked at the G2, the history of the G2, to
7 see what you might need to do to it to make it a safer and
8 better product; right?

9 A Yeah. I believe that's in the 2008-ish kind of time
11:47:33 10 frame.

11 MR. LOPEZ: Could I have, please, Exhibit 4327.

12 Greg, if you could go to page 5.

13 First, before you do that --

14 BY MR. LOPEZ:

11:47:53 15 Q Are you familiar with monthly Global PV reports --

16 A No.

17 Q Who's Tim Ring? Do you know who Tim Ring is?

18 A Yeah, CEO of the company.

19 Q And who is John Weiland?

11:48:11 20 A I think the CFO.

21 Q Do you know who John McDermott is?

22 A He was the president of Bard Peripheral Vascular.

23 Q Doesn't get much higher than that in the company, right?

24 You have two highest guys, two highest gentlemen in the
11:48:29 25 corporate offices in New Jersey and you have the president of

DIRECT EXAMINATION - MICHAEL RANDALL

11:48:31 1 the facility or the -- here in Tempe; right?

2 A Um-hmm.

3 Q Now, this is dated February 10, 2006. Do you see that?

4 A Yes.

11:48:41 5 Q Let's -- and the G2 device that you were looking at to
6 make design changes on was being sold about, what, four or
7 five months, by February of 2006? That sound about right?

8 A I'll take your word for it. Like I said, I started in
9 2006 in April, so I really am not sure when that was

11:49:07 10 introduced into the market.

11 Q You don't know -- so the device that you worked on to
12 improve its design, you're telling us you don't know when that
13 device entered the marketplace, the G2?

14 A I don't recall the exact date.

11:49:18 15 Q Well, was it -- can you give us a month?

16 A Seriously, I don't remember. That was on the market
17 before I even joined the company.

18 MR. LOPEZ: Can we please go to page 5 of this
19 exhibit.

11:49:31 20 First of all, Your Honor, I'd like to offer this into
21 evidence at this time.

22 MR. CONDO: 602. Foundation.

23 THE COURT: Well, 602 isn't the objection to the
24 document coming in. Is there an objection to the document
11:49:46 25 being admitted?

DIRECT EXAMINATION - MICHAEL RANDALL

11:49:50 1 MR. CONDO: It is both hearsay and a 402 objection to
2 the document.

3 THE COURT: Sustained on hearsay.

4 MR. LOPEZ: Your Honor, it's official Bard documents.

11:50:02 5 THE COURT: You have to satisfy 803(6).

6 MR. LOPEZ: I'll just show it to the witness, then.

7 BY MR. LOPEZ:

8 Q Sir, you have a screen right there.

9 You see where it's highlighted? "G2 with caudal
11:50:15 10 improvements initiated." See where I am?

11 A Yes.

12 Q "Project initiated to modify the G2 filter to minimize
13 caudal migration."

14 MR. CONDO: Your Honor, I would object to reading
11:50:28 15 from the document.

16 THE COURT: Sustained. It's not in evidence.

17 MR. LOPEZ: I'm going to cite 801(d)(1)(C) and (D).
18 I mean this is -- I don't think this is hearsay. It's a
19 document that was produced to us in this litigation with
11:51:01 20 Bard's Bates numbers on it.

21 THE COURT: It's an out-of-court declaration offered
22 for the truth of the matter asserted. That satisfies the
23 hearsay requirement under Rule 801.

24 MR. LOPEZ: I'm suggesting 801(d)(1)(2) would suggest
11:51:24 25 it's not. But I understand, Your Honor.

DIRECT EXAMINATION - MICHAEL RANDALL

11:51:31 1 BY MR. LOPEZ:

2 Q Let me ask you this, without looking at a document: When
3 you got involved in the G2 when you were talking -- when it
4 was going to be redesigned to the next generation, whatever
11:51:41 5 design fixes it required, it was the same design, other than
6 the hook on top, that existed since Bard started marketing the
7 G2 correct?

8 A My initial project was adding a snare hook. It was
9 essentially the same filter.

11:52:00 10 Q And all those problems that existed in whenever it was you
11 started talking about making fixes in August of 2008 existed
12 in 2005.

13 A The improvements that I worked on, looking at this, the
14 first time I'm seeing this, it looks like maybe there was some
11:52:20 15 information --

16 MR. LOPEZ: You can take this down.

17 BY MR. LOPEZ:

18 Q My question is, all of the things that -- the design of
19 the G2 that you looked at in 2008 where you were going to make
11:52:32 20 it better, you were going to make it safer, you were going to
21 make design changes, is the exact same device that was on the
22 market in 2005 with the exception that it had a hook at the
23 top of it; correct?

24 A The device that I put the hook on was essentially the same
11:52:50 25 G2.

DIRECT EXAMINATION - MICHAEL RANDALL

11:52:52 1 Q And that's -- I'm sorry.

2 A In terms of it being safe, it was still a safe device.
3 We're making enhancements. We weren't necessarily fixing
4 issues.

11:53:02 5 Q Well, my question is simply this: Whatever it is you were
6 doing as -- you were the project leader; right?

7 A You're talking about for the G2X?

8 Q No. For the enhancement of the G2X. You were the project
9 leader?

11:53:18 10 A Yeah, initially.

11 Q And the device you were looking at to enhance was the G2X;
12 correct?

13 A Correct.

14 Q And the G2X was the G2 with a hook at the top of it;
11:53:29 15 correct?

16 A Correct.

17 MR. LOPEZ: Could we have Exhibit 1878, please.

18 BY MR. LOPEZ:

19 Q Sir, this is an exhibit that you saw before today; right?

11:53:47 20 A Yes.

21 Q It's addressed to you; correct?

22 A Yes.

23 Q And it's from Andre Chanduszko.

24 A Right.

11:53:56 25 Q Who is Mr. Chanduszko?

DIRECT EXAMINATION - MICHAEL RANDALL

11:53:59 1 A Andre is an engineer on the vena cava filter franchise.

2 Q And did you work for him?

3 A No.

4 Q And the subject is EVEREST and MAUDE desktop PowerPoint;
11:54:12 5 correct.

6 A Correct.

7 MR. LOPEZ: Can we have 1222, please, trial exhibit.

8 BY MR. LOPEZ:

9 Q Do you recognize this document?

11:54:24 10 A Yes, I've reviewed it.

11 Q Did you help prepare this document?

12 A I reviewed it. Andre prepared it.

13 Q If we go to the next page of this document, you'll see
14 there's a blank there. That was a picture of you as the G2
11:54:43 15 Platinum project leader, correct, at one time?

16 A There was a picture of me, yes.

17 Q And you were in fact the G2 Platinum project leader;
18 correct?

19 A Initially.

11:54:56 20 MR. LOPEZ: If we go back to the beginning of this
21 PowerPoint.

22 THE WITNESS: Actually, let me clarify. Yes, I was
23 project leader for this one. We had a different project that
24 became Eclipse where I started it and someone else took over.

25

DIRECT EXAMINATION - MICHAEL RANDALL

11:55:11 1 BY MR. LOPEZ:

2 Q And this is a PowerPoint presentation you're familiar
3 with, with respect to the meeting that's being discussed here
4 and the e-mail I just showed you from Mr. Chanduszko; correct?

11:55:20 5 A Yes. This was a draft presentation he sent to me.

6 MR. LOPEZ: I'd like to offer this into evidence at
7 this time, Your Honor.

8 MR. CONDO: No objection.

9 MR. LOPEZ: May we publish it to the jury?

11:55:30 10 THE COURT: By "this," you mean 1222?

11 MR. LOPEZ: I'm sorry. Yes, Your Honor. Exhibit
12 1222.

13 THE COURT: Admitted.

14 (Exhibit 1222 admitted.)

11:55:37 15 MR. LOPEZ: And may I publish it to the jury?

16 THE COURT: Yes.

17 MR. LOPEZ: Thank you.

18 BY MR. LOPEZ:

19 Q Now, this PowerPoint, it's about a meeting that was going
11:55:47 20 to take place. True?

21 A Yes.

22 Q When a company gets ready for a meeting, they're going to
23 be discussing the important things contained in the
24 PowerPoint, do you all sit down and discuss the things that
11:55:59 25 should be on a PowerPoint or presentation to help guide you

DIRECT EXAMINATION - MICHAEL RANDALL

11:56:03 1 through a meeting like that?

2 A Yes.

3 Q And you participated in this; right?

4 A In the creation or in the meeting?

11:56:10 5 Q Well, no, in just the development of the meeting, the
6 agenda, and what it was you all were going to be talking
7 about.

8 A Yes.

9 Q And who else did? Mr. Chanduszko?

11:56:20 10 A Yes.

11 Q How about Rob Carr?

12 A I don't remember.

13 Q Who else do you remember that was on this team that would
14 have been involved in this meeting?

11:56:36 15 A So it was probably a cross-functional team, so whoever was
16 in Quality at the time. I don't know if it was John Conway.
17 He might have been involved in that meeting. The marketing
18 person, which I think was Bret Baird. He was probably in that
19 meeting. Some other cross-functional people. Regulatory or
11:57:00 20 something.

21 Q I'm sorry, I should have done this with Trial Exhibit
22 1878. The date on that was June 9, 2008. Does that sound
23 about the time period this PowerPoint was being created and
24 discussed at Bard?

11:57:14 25 A Yeah, sounds like --

DIRECT EXAMINATION - MICHAEL RANDALL

11:57:15 1 Q If you need to look at the e-mail to refresh your
2 memory -- let's put up 1878. I think the date is important.
3 I want you to confirm that for us.

4 MR. LOPEZ: Put 1878 back up real quickly for us.

11:57:31 5 BY MR. LOPEZ:

6 Q That refresh your recollection that this was on June 9,
7 2008?

8 A June 9. Yeah.

9 MR. LOPEZ: Let's go back, Greg, please, to Trial
11:57:41 10 Exhibit 1222.

11 BY MR. LOPEZ:

12 Q Okay. The objective of the meeting is to analyze EVEREST.
13 What's EVEREST?

14 A EVEREST was the clinical study that was performed on the
11:57:51 15 G2 filter to, I believe, give retrievability indication.

16 Q Let's make sure we're all on the same page about clinical
17 study. This was a clinical study that was done after the G2
18 was already on the market as a permanent device and the
19 purpose and the design of this study was to see if the G2
11:58:13 20 could be retrieved.

21 A I believe so. Yes.

22 Q And by this had -- do I understand you to say that the
23 details and the results of the EVEREST study were discussed at
24 this meeting?

11:58:30 25 A Andre put together some slides on the EVEREST data and it

DIRECT EXAMINATION - MICHAEL RANDALL

1 was discussed.

2 Q Okay. And the objective was to analyze EVEREST and MAUDE
3 and to provide justifications for proposed changes to G2
4 filter; correct?

5 A Yeah, we're looking to see how we can improve the product.

6 Q Yeah. And the new improved filter platform was going to
7 be called the G2 Platinum?

8 A Correct.

9 Q Why Platinum?

10 A We called it G2 Platinum because the scope of this project
11 was to take the filter and we were going to electropolish it.

12 Electropolishing is a like electrical chemical
13 removal of the surface finish on the outside and it leaves the
14 color of the filter almost looking like platinum. So we
15 picked the name G2 Platinum just because it would look like
16 that.

17 MR. LOPEZ: If we can go to the next slide, please,
18 Greg.

19 Next one after that, please.

20 BY MR. LOPEZ:

21 Q Here is the objective of this meeting, right? It says it
22 right here, was to improve the G2 platform to address current
23 complications without a clinical trial. Right?

24 A Yes.

25 Q In other words, you wanted to be able to do something to

DIRECT EXAMINATION - MICHAEL RANDALL

1 the G2 filter to improve it without having to engage in a
2 clinical trial; correct?

3 A Yeah, because there were several projects going on. One
4 would involve a clinical trial, which was being led by another
5 team. And what I was tasked with doing was seeing if we can
6 make improvements early on and faster.

7 So we had parallel paths. One project with a
8 clinical trial, and then another one where what can we do
9 immediately.

10 THE COURT: We're going to break at this point,
11 counsel.

12 Ladies and gentlemen of the jury, we'll excuse you
13 till 1 o'clock.

14 (The jury exited the courtroom at 12:00.)

15 THE COURT: Please be seated.

16 Mr. Lopez --

17 MR. LOPEZ: Yes, sir.

18 THE COURT: -- explain to me that hearsay argument
19 you were making.

20 MR. LOPEZ: I'm just looking at 801(d)(2), opposing
21 party statement. The statement is offered against an opposing
22 party --

23 THE COURT: So you're seeking to admit it as an
24 opposing party admission --

25 MR. LOPEZ: Yes.

DIRECT EXAMINATION - MICHAEL RANDALL

12:01:14 1 THE COURT: -- is that right?

2 MR. LOPEZ: Yes, Your Honor.

3 THE COURT: Okay. You first cited 801(c) --

4 MR. LOPEZ: I know.

12:01:21 5 THE COURT: Then you cited (d)(1).

6 MR. LOPEZ: I was trying to read fast.

7 THE COURT: That's all right. I just wasn't certain.

8 What is your response, Mr. Condo, on 801(d)(2)? And
9 this is with respect to Exhibit 4327, the February 10th, 2006,
12:01:40 10 memo among Bard management.

11 MR. CONDO: None of the elements for that have been
12 established, nor can they be established through this witness.

13 THE COURT: What elements?

14 MR. CONDO: (a), (b), (c), (d) --

12:01:58 15 THE COURT: Well, those are disjunctive. It can be
16 any one of those.

17 MR. CONDO: Right.

18 THE COURT: So how is -- what is your argument as to
19 why this memo is not a statement by Bard?

12:02:15 20 MR. CONDO: Well, you've given me a tough question to
21 answer.

22 THE COURT: Why don't you think about it. You both
23 can think about it. I'll be happy to talk to you about it
24 when we come back from the lunch break.

12:02:26 25 MR. CONDO: Thank you.

DIRECT EXAMINATION - MICHAEL RANDALL

12:02:27 1 THE COURT: And the question that's going to be
2 related to that is whether under Rule 901(a) the fact that
3 it's on Bard letterhead from Bard management to Bard
4 management is sufficient to authenticate it as such a
12:02:54 5 document. And, if so, why then would it not be a statement of
6 Bard under 801(d)(2).

7 MR. CONDO: Understood.

8 THE COURT: So why don't you look at that and I'll be
9 happy to hear from you.

12:03:05 10 Let me ask another question. When we talked about
11 time this morning, Mr. Lopez, and defense counsel, what are
12 your thoughts on the time that's going to be reserved by each
13 side for the punitive damages presentation if the jury finds
14 punitive damages are appropriate? How much time are you going
12:03:26 15 to hold in reserve for that?

16 MR. LOPEZ: I'm thinking 45 minutes, Your Honor, for
17 the plaintiff.

18 MR. NORTH: Your Honor, I was, in abundance of
19 caution, going to reserve between one and two hours.

12:03:43 20 THE COURT: Well, if -- if Bard reserves two hours
21 and plaintiff reserves 45 minutes, that means whenever we send
22 the jury out to deliberate we have to build in the possibility
23 that once they're done we need two hours and 45 minutes of
24 evidence and argument before they go back out to deliberate.
12:04:03 25 Do you all agree with that?

DIRECT EXAMINATION - MICHAEL RANDALL

12:04:06 1 MR. LOPEZ: If I only take forty -- yeah.

2 MR. NORTH: Yes.

3 THE COURT: What is your -- as I look at the
4 calendar, what are your thoughts about splitting the argument
12:04:16 5 between one day and the next? Because that would be -- for
6 example, having plaintiff's opening at the end of the day and
7 defense next morning. Because that's going to affect the
8 timing near the end of the trial as well.

9 MR. LOPEZ: I'm sorry, I didn't follow that. Your
12:04:30 10 Honor. When you say split, you mean plaintiff do --

11 THE COURT: Yeah. For example, you start -- I
12 referred to it as opening -- your closing at, say, 3:30 to
13 4:30, we break for the day, and defendants go the next
14 morning.

12:04:45 15 Parties usually like to do them back to back. But if
16 we're trying to juggle time something like that might be
17 needed.

18 MR. LOPEZ: That's for the first argument? We're not
19 talking about punitives --

12:04:57 20 THE COURT: Not talking -- right.

21 MR. LOPEZ: Whatever it takes. I'd rather argue the
22 same day, but I get rebuttal, so --

23 MR. NORTH: Your Honor, also I believe there will be
24 at least one witness. I mean, it will be a brief witness
12:05:11 25 before the arguments.

12:05:13 1 THE COURT: I'm not talking -- I'm just talking about
2 splitting closings. Not in punitives but at the end of --

3 MR. NORTH: Oh, regular closings.

4 THE COURT: Yeah.

12:05:22 5 MR. NORTH: I think we'd have to do what we have to
6 do with the schedule, Your Honor.

7 THE COURT: Okay. All right. I'll think this over.

8 MR. LOPEZ: Thank you, Your Honor.

9 THE COURT: Let's plan to be back here at five to
12:05:32 10 1:00 so we can talk about 801(d)(2).

11 (Recess taken at 12:05.)

12 (End of a.m. session transcript.)

13 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 21st day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter